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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,344	11/08/2001	Peter K. Law	37794-0032	5167

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,344	LAW, PETER K.	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 Nov. 2004 and 22 Feb. 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *attached* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0-0.

DETAILED ACTION

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1632.

As indicated in the attached interview summary, claims 33, 34, 42, and 46 presented in the amendment filed 2/22/05 did not include intended changes that had been presented in the non-compliant amendment filed 11/01/04. Applicant's attorney indicated that this was an oversight in preparing the amendment of 2/22/05. It was agreed that claims 33, 34, 42, and 46 would be examined as if the changes presented in the 11/1/04 amendment were present. Applicant is required to make the agreed upon amendments in response to this Office action.

Information Disclosure Statement

Applicant's intent to file an information disclosure statement listing non-patent literature documents filed, but not listed on the IDS of 1/15/03 is acknowledged. However, no such IDS has been received. Applicant is reminded that an IDS filed after final rejection must comply with 37 CFR 1.97(d), i.e. it must include the statement specified in § 1.97(e) and the fee set forth in § 1.17(p).

Specification

The disclosure is objected to because of the following informalities: page 13, line 31, recites "08/477,377". The status of this application has changed, and should be indicated in the specification. Insertion of --, now abandoned-- after the application number would be remedial.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 34-36 and 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 43 recite the limitation "the donor's skeletal muscle tissue" in line 2 of each. There is insufficient antecedent basis for this limitation in the claim. Replacing "the" in the phrase with -- a -- would be remedial.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-51 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al (The Journal of Neuroscience 14:4805-4814, 1994) in view of Beutler et al (Journal of Neurochemistry 64:475-481, 1995), Deglon et al (Human Gene Therapy 7:2135-2146, 1996), Law (WO 96/18303, 1996), Law et al (Cell Transplantation 2:485-505, 1993), Allen and Rankin (Proceedings of the Experimental Biology and Medicine 194:81-86, 1990) and Morris and Herz

(Naunyn Schmiedebergs Arch. Pharmacol. 336:240-243, 1987 (abstract only) for the reasons of record set forth in the Office action of 6/1/04.

Applicant's arguments filed 11/1/04 have been fully considered but they are not persuasive. Applicant takes issue with the characterization of using myoblasts for *ex vivo* gene therapy as being routine because the cited references must have been considered to be novel and pioneering to have been published. However, if this were the standard for publication, follow-up studies and practical applications would never be published. Applicant has provided no evidence to support their assertion. Furthermore, the claims do not exclude research applications of the method, such as studying the biological effects of opioids, such as described in Wu. The claims are directed to delivering an opioid to the CNS by implantation of recombinant muscle cells that secrete the opioid, including myoblasts, into certain muscles. The purpose of the method, whether research or therapy, is not limited by the claims.

Applicant argues that no successful human work is cited, and suggests that recitation of "patient" limits the claims to human, and that the myoblasts of Deglon are not human muscle cells. In response, a showing of obviousness requires only evidence of reasonable expectation of success. Applicant has not explained or provided evidence that success in animals models does not provide reasonable expectation of success. Also, the instant specification also fails to demonstrate "successful human work." If the absence of such work is evidence of the lack of expectation of success, then the instant specification suffers the same defect. Is Applicant suggesting that the instant specification is not enabling? Furthermore, the claims are not limited

to humans, nor does the instant specification indicate that "patient" refers specifically to human subjects. Non-human mammals are the patients treated by veterinarians.

Applicant admits that it was well known that myoblasts could be added to animal's muscle, but notes that the claims are not directed to myoblast therapy *per se*. While the claims are not limited to the use of myoblasts, they do embrace the use of myoblasts. The experience in the art with myoblast therapy is relevant to the claimed invention, since in at least some embodiments myoblasts are used, and the prior art experience with them and how they perform when implanted into muscle tissue *in vivo* is clearly relevant to aspects of the claimed invention.

Applicant argues that the claimed method involves "allogenic cells, manipulating those cells to incorporate a specific kind of expressed transgene, and then implanting those altered cells into a very special type of organ located at a very special type of location to take advantage of a very special type of delivery", and that Wu uses different cells for a different purpose. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Also, Applicant points out that Wu is directed to studying tolerance to opioids, and shows that implanting cells in body spaces is undesirable, since tolerance was induced. Applicant (Reply of 11/01/04, page 9) to list a series of perceived advantages of the claimed method. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not exclude the development of tolerance. Furthermore, the instant specification provides no experimental evidence that tolerance would not be induced by intramuscular implantation of the cells. The examples presented in the specification are prophetic, and the specification does not mention tolerance to opioids at all. The impetus of the claimed invention is indicated as being to offer a more long term and safer solution to implantation of xenogeneic cells into fluid spaces of the CNS. The cited prior art, when taken in combination, suggests the same.

With respect to the choice of muscles, Morris and Herz was cited to provide the reason why it would have been obvious to choose these muscles. With respect to fat cells, claim 42 does not embrace the use of fat cells, but rather implantation of muscle cells into a region of the body that contains fat cells. Muscles are regions of the body that contain fat cells, as anyone who fish, fowl, or mammal meat knows from experience.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1632